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Therapeutic Goods Amendment Regulations 2000 (No. 7)¹

Statutory Rules 2000 No. ²

358

I, WILLIAM PATRICK DEANE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated 13 DEC 2000 2000

WILLIAM DEANE
Governor-General

By His Excellency's Command

GRANT TAMBLING
Parliamentary Secretary to the Minister for Health
and Aged Care

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2000 (No. 2)*.

7

2 Commencement

These Regulations commence on gazettal.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments

(regulation 3)

[1] Regulation 2, after definition of *antiseptic*

insert

authorised person has the meaning given in regulation 47AA.

[2] Regulation 2, definition of *ethics committee*

omit

[3] Regulation 2, after definition of *Poisons Standard*

insert

Practice Guidelines has the meaning given by paragraph 12AB (2) (a).

principal investigator, in relation to a clinical trial of therapeutic goods, means the person who is in charge of the conduct of the trial.

[4] Regulation 2, after definition of *serious*

insert

specialist has the same meaning as in the *Health Insurance Act 1973*.

[5] Subregulation 12 (1)

omit

Act.

insert

Act (except section 31A and sections 31C to 31F).

[6] Subregulation 12 (1A)

after

Part 3 of the Act

insert

(except section 31A and sections 31C to 31F)

[7] Subregulation 12 (2)

substitute

(2) If:

- (a) therapeutic goods that, in relation to a provision of Part 3 of the Act, are exempt goods cease to be exempt goods; and
 - (b) the sponsor of the goods has applied for registration or listing of the goods before the goods cease to be exempt goods;
- the goods are taken to be exempt goods until the application for registration or listing is determined.

[8] Subregulation 12A (1)*omit*

Act.

insert

Act (except section 31A and sections 31C to 31F).

[9] After regulation 12A*insert***12AA Applications for special and experimental uses**

Without limiting the information that may be required by the Secretary under subsection 19 (2) of the Act, that information may include, in relation to therapeutic goods the subject of an application under subsection 19 (1) of the Act for a use described in paragraph 19 (1) (b) of the Act:

- (a) the names of the members of the ethics committee that has given approval for each proposed clinical trial of the goods and that will have responsibility for monitoring the conduct of each trial; and
- (b) the name of, and the contact details for, the principal investigator for each trial; and
- (c) the name of the person who will be in charge of the trial site (or each trial site, if the trial is to be conducted at more than 1 site), unless that person is the principal investigator; and
- (d) information about whether or not any conditions specified by the committee have been met.

12AB Goods imported, etc, for experimental uses

- (1) For subsection 19 (1A) of the Act, this regulation specifies conditions attaching to an approval for the importation, exportation or supply of therapeutic goods for use solely for experimental purposes in humans.
- (2) Before any clinical trials proposed to be undertaken in relation to the goods are started, the National Manager, Therapeutic Goods Administration, must receive from the person to whom the approval is granted, and the principal investigator for each trial site:
 - (a) a written assurance that clinical trials will be conducted in accordance with the Guidelines for Good Clinical Practice (the *Practice Guidelines*), as in force from time to time, published jointly by the International Conference on Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use and the Committee for Medicinal Products; and
 - (b) a written undertaking:
 - (i) to comply with requests by an authorised person, whether made before or after the start of the trial, to give information about the conduct of the trial; and
 - (ii) allow an authorised person to do the things mentioned in regulation 12AC.

12AC Powers of authorised persons in relation to goods imported, etc, for experimental uses

- (1) An authorised person may, in relation to a clinical trial mentioned in regulation 12AB:
 - (a) enter the site of the trial; and
 - (b) search the site and any thing on the site; and
 - (c) inspect, examine, take measurements of, or conduct tests on (including by the taking of samples), any thing on the site that relates to the trial; and

- (d) take photographs, make video recordings or make sketches of the site or any thing on the site; and
 - (e) inspect any book, record or document on the site that relates to the trial; and
 - (f) request the principal investigator to:
 - (i) answer any questions put by the authorised person; and
 - (ii) produce any book, record or document requested by the authorised person.
- (2) An authorised person is not entitled to do a thing mentioned in subregulation (1) if:
- (a) the principal investigator, or any other person present at the site concerned and in apparent control, requests the authorised person to produce his or her identity card for inspection; and
 - (b) the authorised person fails to comply with the request.
- Note* For identity cards, see section 52 of the Act.
- (3) The principal investigator, or any other person present at the site and in apparent control, is entitled to observe a search conducted under paragraph (1) (b), but must not impede the search.
- (4) Subregulation (3) does not prevent 2 or more areas of the site being searched at the same time.

12AD Use of goods for experimental purposes — specified conditions

For subsection 19 (4A) of the Act, the following conditions are specified:

- (a) the use of therapeutic goods in a clinical trial must be in accordance with the Practice Guidelines;

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- (b) the use must comply with a procedural protocol determined by the ethics committee that gave approval for the clinical trial of the goods and that has the function of monitoring the conduct of the trial at each trial site;
 - (c) the use must be in accordance with the ethical standards set out in the National Statement on Ethical Conduct in Research Involving Humans, as in force from time to time, published by the National Health and Medical Research Council;
 - (d) the use must cease if the ethics committee mentioned in paragraph (b) informs the principal investigator that the use is inconsistent with:
 - (i) the protocol mentioned in paragraph (b); or
 - (ii) any condition subject to which approval for the use was given.

[10] Subregulation 12B (1)

substitute

- (1) For paragraph 19 (6) (a) of the Act, in relation to therapeutic goods that are medicines, a medical practitioner is in the prescribed class of medical practitioners if he or she is engaged in clinical practice outside a hospital and:
 - (a) has demonstrated that, in relation to the proposed supply, he or she does not have access to an ethics committee that could approve the supply; and
 - (b) has, from a specialist college having an established expertise relevant to use of the medicines concerned, endorsement to supply the medicines.

[11] Paragraph 12B (4) (a)*substitute*

- (a) that, in each case, the medical practitioner authorised under subsection 19 (5) of the Act:
- (i) is a specialist engaged in clinical practice at a hospital; and
 - (ii) is endorsed by the relevant ethics committee of the hospital; and

[12] After regulation 47A*insert***47AA Authorised persons**

An authorised person under paragraph (a) of the definition of *authorised person* in subsection 3 (1) of the Act is authorised to exercise powers given to an authorised person under a provision of these Regulations.

[13] Regulation 47B*substitute***47B Provision of information concerning medicines and therapeutic devices**

- (1) The following persons must provide a report to the Secretary every 6 months:
- (a) a delegate under subsection 57 (3) of the Act;
 - (b) a person authorised under subsection 19 (5) of the Act to supply a medicine or therapeutic device;
 - (c) a sponsor of therapeutic goods.
- (2) The report must be in a form approved by the Secretary.

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- (3) A report by a person mentioned in paragraph (1) (a) must:
- (a) list each item of therapeutic goods (including therapeutic devices) approved by the person during the period to which the report relates; and
 - (b) state the number of new approvals, and the number of repeat approvals, of medicines and therapeutic devices that the person gave during that period.
- (4) A report by a person mentioned in paragraph (1) (b) must list each item of therapeutic goods (including therapeutic devices) supplied by the person during the period to which the report relates.
- (5) A report by a sponsor must:
- (a) list each kind of therapeutic goods supplied by the sponsor during the period to which the report relates; and
 - (b) state the number of times therapeutic goods have been supplied to medical practitioners, and the quantity supplied:
 - (i) to which section 18 of the Act applies; and
 - (ii) to which paragraph 19 (1) (a) of the Act applies; and
 - (iii) to which paragraph 19 (1) (b) of the Act applies; and
 - (iv) to which subsection 19 (5) of the Act applies.

[14] Schedule 5A, item 3, column 3, paragraph (f)

omit

trial.

insert

trial; and

[15] Schedule 5A, item 3, column 3, after paragraph (f)*insert*

- (g) the conditions set out in regulation 12AD must be complied with, as if that regulation applied to a person using therapeutic goods under this item

Notes

1. These Regulations amend Statutory Rules 1990 No. 394, as amended by 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332, 370 and 430; 1993 No. 141; 1994 Nos. 150, 222 and 364; 1995 Nos. 33, 111, 192, 208, 253, 320 and 328; 1996 Nos. 9, 25 (disallowed by the House of Representatives on 10 September 1996), 131, 200 and 208; 1997 Nos. 162, 398, 399, 400 and 401 (disallowed by the Senate on 31 March 1998); 1998 Nos. 227, 247 and 369; 1999 Nos. 62, 209 and 324; 2000 Nos. 29, 48, 70, 123, 124 and 267.

2. Notified in the *Commonwealth of Australia Gazette* on / 2000. 20 December